

#15

9/19/03

PTO/SB/68 (04-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST FOR ACCESS TO AN APPLICATION UNDER 37 CFR 1.14(e)

In re Application of _____

Application Number

08/246,034

Filed

5/18/94

Art Unit

Examiner

Paper No. _____

Assistant Commissioner for Patents
Washington, DC 20231

1. ☒ I hereby request access under 37 CFR 1.14(e)(2) to the application file record of the above-identified ABANDONED Application, which is not within the file jacket of a pending Continued Prosecution Application (CPA) (37 CFR 1.53(d)) and is: (CHECK ONE)

☒ (A) referred to in:

United States Patent Application Publication No. _____, page _____, line _____.

United States Patent Number 6509006, column Face, line _____, or

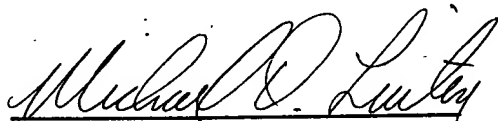
an International Application which was filed on or after November 29, 2000 and which

designates the United States, WIPO Pub. No. _____, page _____, line _____.

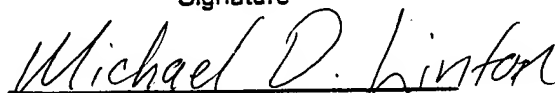
☐ (B) referred to in an application that is open to public inspection as set forth in 37 CFR 1.11(b) or

1.14(e)(2)(i), i.e., Application No. _____, paper No. _____, page _____, line _____.

2. ☐ I hereby request access under 37 CFR 1.14(e)(1) to an application in which the applicant has filed an authorization to lay open the complete application to the public.



Signature

8/15/03
Date

Typed or printed name

FOR PTO USE ONLY

Approved by: _____

(initials)

Unit: _____

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



US006509006B1

(12) **United States Patent**
Platz et al.

(10) **Patent No.:** **US 6,509,006 B1**
 (45) **Date of Patent:** **Jan. 21, 2003**

(54) **DEVICES COMPOSITIONS AND METHODS FOR THE PULMONARY DELIVERY OF AEROSOLIZED MEDICAMENTS**

(75) **Inventors:** **Robert M. Platz**, Half Moon Bay, CA (US); **John S. Patton**, San Carlos, CA (US); **Linda Foster**, Sunnyvale, CA (US); **Mohammed Eljamal**, San Jose, CA (US)

(73) **Assignee:** **Inhale Therapeutic Systems, Inc.**, San Carlos, CA (US)

(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) **Appl. No.:** **09/427,075**

(22) **Filed:** **Oct. 26, 1999**

Related U.S. Application Data

(63) Continuation-in-part of application No. 08/417,507, filed on Apr. 4, 1995, now abandoned, and a continuation of application No. 08/383,475, filed on Feb. 1, 1995, and a continuation of application No. 08/313,707, filed on Sep. 27, 1994, and a continuation of application No. 08/309,691, filed on Sep. 21, 1994, and a continuation of application No. 08/246,034, filed on May 18, 1994, and a continuation of application No. 08/232,849, filed on Apr. 25, 1994, and a continuation of application No. 08/044,358, filed on Apr. 7, 1993, and a continuation-in-part of application No. 07/910,048, filed on Jul. 8, 1992.

(51) **Int. Cl.⁷** **A61K 9/12; A61K 9/14**
 (52) **U.S. Cl.** **424/46; 424/45; 424/489**
 (58) **Field of Search** **424/45, 46, 489**

(56) References Cited

U.S. PATENT DOCUMENTS

2,598,525 A 5/1952 Fox
 3,202,731 A 8/1965 Grevenstuck et al.
 3,300,474 A 1/1967 Flodin et al.
 3,314,803 A 4/1967 Tarrytown et al.
 3,362,405 A 1/1968 Hazel
 3,425,600 A 2/1969 Abplanalp
 3,540,927 A 11/1970 Niimi et al.
 3,554,768 A 1/1971 Feldman
 3,608,066 A 9/1971 Illartein
 3,620,776 A 11/1971 Mishkin et al.
 3,666,496 A 5/1972 Honey et al.
 3,674,901 A 7/1972 Shepherd et al.
 3,764,716 A 10/1973 Rainwater et al.
 3,921,637 A 11/1975 Bennie et al.
 3,964,483 A 6/1976 Mathes
 3,971,852 A 7/1976 Brenner et al.
 3,991,304 A 11/1976 Hillsman
 3,991,761 A 11/1976 Cocozza
 3,994,421 A 11/1976 Hansen
 4,036,223 A 7/1977 Obert
 4,069,819 A 1/1978 Valentini et al.
 4,098,273 A 7/1978 Glenn
 4,109,019 A 8/1978 Moore
 4,153,689 A 5/1979 Hiral et al.
 4,206,200 A 6/1980 Guthöhrlein et al.
 4,249,526 A 2/1981 Dean et al.
 4,253,468 A 3/1981 Lehmbeck

4,294,624 A 10/1981 Veltman
 4,294,829 A 10/1981 Suzuki et al.
 4,338,931 A 7/1982 Cavazza
 4,423,079 A 12/1983 Kline
 4,446,862 A 5/1984 Baum et al.
 4,452,239 A 6/1984 Malem
 4,484,577 A 11/1984 Sackner et al.
 4,503,035 A 3/1985 Pestka et al.
 4,533,552 A 8/1985 Kawamata et al.
 4,534,343 A 8/1985 Nowacki et al.

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

BE 902 257 8/1985
 DE 18 12 574 6/1970
 DE 24 15 159 10/1975
 DE 31 41 498 4/1983
 DE 01 61 072 9/1984
 EP 0 015 123 9/1980

(List continued on next page.)

OTHER PUBLICATIONS

US 5,849,884, 12/1998, Wolszwillo et al. (withdrawn)

J. Hanes et al. (1997). Proc. Int'l Symp. Control Rel. Bioactive Matter 24:57-58.*

Andrew, Edmund L., "Gelatin Capsules Revamped For New Generation Of Pills," *New York Times*, Saturday, Sep. 16, 1992, 19 (N), 35 (L), col 5, 9 col in.

Annear, D. I., "Observations on Drying Bacteria From the Forzen and From the Liquid State," *Austral. J. Exp. Biol.* vol. 36, pp. 211-221.

(List continued on next page.)

Primary Examiner—Jose' G. Dees

Assistant Examiner—Mina Haghighatian

(74) *Attorney, Agent, or Firm*—Burns Doane Swecker & Mathis LLP

(57) ABSTRACT

According to the subject invention, dispersible dry powder pharmaceutical-based compositions are provided, including methods for their manufacture and dry powder dispersion devices. A dispersible dry powder pharmaceutical-based composition is one having a moisture content of less than about 10% by weight (% w) water, usually below about 5% w and preferably less than about 3% w; a particle size of about 1.0–5.0 μ m mass median diameter (MMD), usually 1.0–4.0 μ m MMD, and preferably 1.0–3.0 μ m MMD; a delivered dose of about >30%, usually >40%, preferably >50%, and most preferred >60%; and an aerosol particle size distribution of about 1.0–5.0 μ m mass median aerodynamic diameter (MMAD), usually 1.5–4.5 μ m MMAD, and preferably 1.5–4.0 MMAD. Such composition are of pharmaceutical grade purity.

2 Claims, No Drawings